MAY 1 5 2001

K001694

APPENDIX B – 510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared;

a. Submitter:

Guidant Corporation
1525 O'Brien Drive
Menlo Park, CA 94025
(650) 470-6200 (phone)
(650) 470-6320 (fax)

b. Official Correspondent:

Bernice Jurs
Senior Regulatory Affairs Associate
Guidant Cardiac and Vascular Surgery
1525 O'Brien Drive
Menlo Park, CA 94025
(650) 470-6200 (phone)
(650) 470-6320 (fax)

Bernice Jurs

c. Date Summary Prepared: May 31, 2000

2. Name of device, including trade name and classification name:

a.	Trade/Proprietary Name:	Guidant Retriever Device
b.	Common or Usual Name:	Endovascular Snare
c.	Classification Name:	Diagnostic intravascular catheter

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company:	Target Therapeutics
Device:	Retriever II
510(k) :	K964210
Date Cleared:	October 31, 1997

4. **A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

The Guidant Retriever Device is a sterile, single-use, disposable endovascular snare designed for use in retrieving intravascular occlusion coils misplaced during interventional radiological procedures in the peripheral and neuro vasculature. The Guidant Retriever Device consists of four main components: a basket, a tip, a core wire, and an introducer sheath. The basket at the distal end is used to ensnare the coil which is being retrieved. The flexible tip facilitates positioning of the device. The core wire enables the device to be advanced and retracted through a standard 0.018" braided microcatheter. The device is packaged within a disposable introducer sheath.

The Guidant Retriever Device is used by being placed distal to the obstructing coil using a microcatheter as a delivery sheath small enough to cross past the obstruction. Once past the obstruction, the basket can be unsheathed allowing it to self expand to the vessel diameter. The mesh pattern of the basket facilitates ensnaring and containing a coil by providing a multitude of surfaces upon which the coil can become hooked or entangled and subsequently removed from the body.

5. **Statement of intended use:**

The Guidant Retriever Device is indicated for use in the retrieval of intravascular occlusion coils misplaced during interventional radiological procedures in the peripheral and neuro vasculature.

6. **Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.**

The Guidant Retriever Device contains similar materials, is of similar design, and has the same operating principle as the predicate device. All materials used in the manufacture of the Guidant Retriever Device are commonly used in medical applications or have been proven to be biocompatible through biocompatibility testing.

7. **Brief summary of nonclinical tests and results:**

Bench testing (tensile test, turns to failure, tip buckling test) and testing in animals indicate that the device performs safely and effectively when used in accordance with the Instructions for Use. The Guidant Retriever Device does not raise any new safety, effectiveness, or performance issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 5 2001

Ms. Jacqueline J. Jackson
Manager Regulatory Affairs
Guidant Corporation
Cardiac and Vascular Surgery Group
1525 O'Brien Drive
Menlo Park, CA 94025

Re: K001694
Trade Name: Guidant NEURONET™ Endovascular Snare
Regulation Number: 870.1250
Regulatory Class: II (two)
Product Code: DQY
Dated: February 13, 2001
Received: February 14. 2001

Dear Ms. Jackson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001694

Device Name: Guidant Retriever Device

Indications for Use:

The Guidant Retriever Device is indicated for use in the retrieval of intravascular occlusion coils misplaced during interventional radiological procedures in peripheral and neuro vasculature.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001694

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)